AO 440 (Rev. 8/01) Summons in a Civil Action

# UNITED STATES DISTRICT COURT

Southern District of New York

Jose Escobar

V.

Merck & Company, INC.

**SUMMONS IN A CIVIL ACTION**

CASE NUMBER: 08 CV 4104

JUDGE LEISURE

TO: (Name and address of Defendant)

Merck & Co., Inc.
One Merck Drive
Whitehouse Station, NJ 08889-0100

**YOU ARE HEREBY SUMMONED** and required to serve on PLAINTIFF'S ATTORNEY (name and address)

Victoria J. Maniatis, Esq.
Morelli Ratner PC
950 Third Avenue
New York, NY 10022

an answer to the complaint which is served on you with this summons, within _____ days after service of this summons on you, exclusive of the day of service. If you fail to do so, judgment by default will be taken against you for the relief demanded in the complaint. Any answer that you serve on the parties to this action must be filed with the Clerk of this Court within a reasonable period of time after service.

J. MICHAEL McMAHON

CLERK

MAY 01 2008

DATE

(By) DEPUTY CLERK

AO 440 (Rev. 8/01) Summons in a Civil Action

## RETURN OF SERVICE

| | |
|---|---|
| Service of the Summons and complaint was made by me[1] | DATE |
| NAME OF SERVER *(PRINT)* | TITLE |

*Check one box below to indicate appropriate method of service*

☐ Served personally upon the defendant. Place where served:

☐ Left copies thereof at the defendant's dwelling house or usual place of abode with a person of suitable age and discretion then residing therein.

Name of person with whom the summons and complaint were left:

☐ Returned unexecuted:

☐ Other (specify):

## STATEMENT OF SERVICE FEES

| TRAVEL | SERVICES | TOTAL $0.00 |
|---|---|---|

## DECLARATION OF SERVER

I declare under penalty of perjury under the laws of the United States of America that the foregoing information contained in the Return of Service and Statement of Service Fees is true and correct.

Executed on _____ _____
Date *Signature of Server*

_____
*Address of Server*

(1) As to who may serve a summons see Rule 4 of the Federal Rules of Civil Procedure.

JUDGE LEISURE

JS 44C/SDNY
REV. 12/2005

# CIVIL COVER SHEET

08 CV 4104

The JS-44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for use of the Clerk of Court for the purpose of initiating the civil docket sheet.

PLAINTIFFS
Jose Escobar

DEFENDANTS
Merck & Company Inc.
One Merck Drive
Whitehouse Station, NJ 08889

RECEIVED
MAY 01 2008
U.S.D.C. S.D. N.Y.
CASHIERS

ATTORNEYS (FIRM NAME, ADDRESS, AND TELEPHONE NUMBER
Morelli Ratner PC; 950 Third Avenue
New York, NY 10022 (212)751 9800

ATTORNEYS (IF KNOWN)
Venable LLP; Two Hopkins Plaza, Suite 1800
Baltimore, MD (410) 244-7400

CAUSE OF ACTION (CITE THE U.S. CIVIL STATUTE UNDER WHICH YOU ARE FILING AND WRITE A BRIEF STATEMENT OF CAUSE)
28 U.S.C. § 1332; Diversity of Citizenship. Plaintiff, a Florida resident, sustained personal injury as a result of Defendant's Pharmaceutical drug Fosamax

Has this or a similar case been previously filed in SDNY at any time? No [X] Yes? [ ] Judge Previously Assigned

If yes, was this case Vol [ ] Invol. [ ] Dismissed. No [ ] Yes [ ] If yes, give date _____ & Case No. _____

*(PLACE AN [x] IN ONE BOX ONLY)* NATURE OF SUIT

**CONTRACT**
- [ ] 110 INSURANCE
- [ ] 120 MARINE
- [ ] 130 MILLER ACT
- [ ] 140 NEGOTIABLE INSTRUMENT
- [ ] 150 RECOVERY OF OVERPAYMENT & ENFORCEMENT OF JUDGMENT
- [ ] 151 MEDICARE ACT
- [ ] 152 RECOVERY OF DEFAULTED STUDENT LOANS (EXCL VETERANS)
- [ ] 153 RECOVERY OF OVERPAYMENT OF VETERAN'S BENEFITS
- [ ] 160 STOCKHOLDERS SUITS
- [ ] 190 OTHER CONTRACT
- [ ] 195 CONTRACT PRODUCT LIABILITY
- [ ] 196 FRANCHISE

**REAL PROPERTY**
- [ ] 210 LAND CONDEMNATION
- [ ] 220 FORECLOSURE
- [ ] 230 RENT LEASE & EJECTMENT
- [ ] 240 TORTS TO LAND
- [ ] 245 TORT PRODUCT LIABILITY
- [ ] 290 ALL OTHER REAL PROPERTY

**TORTS**

**PERSONAL INJURY**
- [ ] 310 AIRPLANE
- [ ] 315 AIRPLANE PRODUCT LIABILITY
- [ ] 320 ASSAULT, LIBEL & SLANDER
- [ ] 330 FEDERAL EMPLOYERS' LIABILITY
- [ ] 340 MARINE
- [ ] 345 MARINE PRODUCT LIABILITY
- [ ] 350 MOTOR VEHICLE
- [ ] 355 MOTOR VEHICLE PRODUCT LIABILITY
- [ ] 360 OTHER PERSONAL INJURY

**PERSONAL INJURY**
- [ ] 362 PERSONAL INJURY - MED MALPRACTICE
- [X] 365 PERSONAL INJURY PRODUCT LIABILITY
- [ ] 368 ASBESTOS PERSONAL INJURY PRODUCT LIABILITY

**PERSONAL PROPERTY**
- [ ] 370 OTHER FRAUD
- [ ] 371 TRUTH IN LENDING
- [ ] 380 OTHER PERSONAL PROPERTY DAMAGE
- [ ] 385 PROPERTY DAMAGE PRODUCT LIABILITY

**ACTIONS UNDER STATUTES**

**CIVIL RIGHTS**
- [ ] 441 VOTING
- [ ] 442 EMPLOYMENT
- [ ] 443 HOUSING ACCOMMODATIONS
- [ ] 444 WELFARE
- [ ] 445 AMERICANS WITH DISABILITIES - EMPLOYMENT
- [ ] 446 AMERICANS WITH DISABILITIES -OTHER
- [ ] 440 OTHER CIVIL RIGHTS

**PRISONER PETITIONS**
- [ ] 510 MOTIONS TO VACATE SENTENCE 28 USC 2255
- [ ] 530 HABEAS CORPUS
- [ ] 535 DEATH PENALTY
- [ ] 540 MANDAMUS & OTHER
- [ ] 550 CIVIL RIGHTS
- [ ] 555 PRISON CONDITION

**FORFEITURE/PENALTY**
- [ ] 610 AGRICULTURE
- [ ] 620 FOOD & DRUG
- [ ] 625 DRUG RELATED SEIZURE OF PROPERTY 21 USC 881
- [ ] 630 LIQUOR LAWS
- [ ] 640 RR & TRUCK
- [ ] 650 AIRLINE REGS
- [ ] 660 OCCUPATIONAL SAFETY/HEALTH
- [ ] 690 OTHER

**LABOR**
- [ ] 710 FAIR LABOR STANDARDS ACT
- [ ] 720 LABOR/MGMT RELATIONS
- [ ] 730 LABOR/MGMT REPORTING & DISCLOSURE ACT
- [ ] 740 RAILWAY LABOR ACT
- [ ] 790 OTHER LABOR LITIGATION
- [ ] 791 EMPL RET INC SECURITY ACT

**ACTIONS UNDER STATUTES**

**BANKRUPTCY**
- [ ] 422 APPEAL 28 USC 158
- [ ] 423 WITHDRAWAL 28 USC 157

**PROPERTY RIGHTS**
- [ ] 820 COPYRIGHTS
- [ ] 830 PATENT
- [ ] 840 TRADEMARK

**SOCIAL SECURITY**
- [ ] 861 HIA (1395FF)
- [ ] 862 BLACK LUNG (923)
- [ ] 863 DIWC (405(g))
- [ ] 863 DIWW (405(g))
- [ ] 864 SSID TITLE XVI
- [ ] 865 RSI (405(g))

**FEDERAL TAX SUITS**
- [ ] 870 TAXES
- [ ] 871 IRS-THIRD PARTY 20 USC 7609

**OTHER STATUTES**
- [ ] 400 STATE REAPPORTIONMENT
- [ ] 410 ANTITRUST
- [ ] 430 BANKS & BANKING
- [ ] 450 COMMERCE/ICC RATES/ETC
- [ ] 460 DEPORTATION
- [ ] 470 RACKETEER INFLUENCED & CORRUPT ORGANIZATION ACT (RICO)
- [ ] 480 CONSUMER CREDIT
- [ ] 490 CABLE/SATELLITE TV
- [ ] 810 SELECTIVE SERVICE
- [ ] 850 SECURITIES/ COMMODITIES/ EXCHANGE
- [ ] 875 CUSTOMER CHALLENGE 12 USC 3410
- [ ] 891 AGRICULTURE ACTS
- [ ] 892 ECONOMIC STABILIZATION ACT
- [ ] 893 ENVIRONMENTAL MATTERS
- [ ] 894 ENERGY ALLOCATION ACT
- [ ] 895 FREEDOM OF INFORMATION ACT
- [ ] 900 APPEAL OF FEE DETERMINATION UNDER EQUAL ACCESS TO JUSTICE
- [ ] 950 CONSTITUTIONALITY OF STATE STATUTES
- [ ] 890 OTHER STATUTORY ACTIONS

*Check if demanded in complaint:*

CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23

DO YOU CLAIM THIS CASE IS RELATED TO A CIVIL CASE NOW PENDING IN S.D.N.Y.? IF SO, STATE:

DEMAND $ 10,000,000 OTHER _____ JUDGE Hon. John F. Keenan DOCKET NUMBER _____

*Check YES only if demanded in complaint*
JURY DEMAND: [X] YES [ ] NO

NOTE: Please submit at the time of filing an explanation of why cases are deemed related.

(SEE REVERSE)

(PLACE AN x IN ONE BOX ONLY) **ORIGIN**

☒ 1 Original Proceeding ☐ 2a. Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from (Specify District) ☐ 6 Multidistrict Litigation ☐ 7 Appeal to District Judge from Magistrate Judge Judgment

☐ 2b. Removed from State Court AND at least one party is a pro se litigant

(PLACE AN x IN ONE BOX ONLY) **BASIS OF JURISDICTION** ***IF DIVERSITY, INDICATE CITIZENSHIP BELOW. (28 USC 1332, 1441)***

☐ 1 U.S. PLAINTIFF ☐ 2 U.S. DEFENDANT ☐ 3 FEDERAL QUESTION (U.S. NOT A PARTY) ☒ 4 DIVERSITY

CITIZENSHIP OF PRINCIPAL PARTIES (FOR DIVERSITY CASES ONLY)

(Place an [X] in one box for Plaintiff and one box for Defendant)

| | PTF | DEF | | PTF | DEF | | PTF | DEF |
|---|---|---|---|---|---|---|---|---|
| CITIZEN OF THIS STATE | [ ] 1 | [ ] 1 | CITIZEN OR SUBJECT OF A FOREIGN COUNTRY | [ ] 3 | [ ] 3 | INCORPORATED and PRINCIPAL PLACE OF BUSINESS IN ANOTHER STATE | [ ] 5 | [x] 5 |
| CITIZEN OF ANOTHER STATE | [x] 2 | [ ] 2 | INCORPORATED or PRINCIPAL PLACE OF BUSINESS IN THIS STATE | [ ] 4 | [ ] 4 | FOREIGN NATION | [ ] 6 | [ ] 6 |

PLAINTIFF(S) ADDRESS(ES) AND COUNTY(IES)

Jose Escobar
10901 Oldham Road
Port Richey, FL 34668

DEFENDANT(S) ADDRESS(ES) AND COUNTY(IES)

Merck & Company Inc.
One Merck Drive
Whitehouse Station, NJ 08889

DEFENDANT(S) ADDRESS UNKNOWN
REPRESENTATION IS HEREBY MADE THAT, AT THIS TIME, I HAVE BEEN UNABLE, WITH REASONABLE DILIGENCE, TO ASCERTAIN THE RESIDENCE ADDRESSES OF THE FOLLOWING DEFENDANTS:

Check one: THIS ACTION SHOULD BE ASSIGNED TO: ☐ WHITE PLAINS ☒ FOLEY SQUARE
(DO NOT check either box if this a PRISONER PETITION.)

DATE 4-28-08 SIGNATURE OF ATTORNEY OF RECORD

ADMITTED TO PRACTICE IN THIS DISTRICT
[ ] NO
[x] YES (DATE ADMITTED Mo. Jan Yr. 2001)
Attorney Bar Code #

RECEIPT #

Magistrate Judge is to be designated by the Clerk of the Court.

Magistrate Judge _____ is so Designated.

J Michael McMahon, Clerk of Court by _____ Deputy Clerk, DATED _____.

UNITED STATES DISTRICT COURT (NEW YORK SOUTHERN)

JUDGE LEISURE

08 CV 4104

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK
==========X

JOSE ESCOBAR



COMPLAINT

Docket No.:

PLAINTIFF,

v.

PLAINTIFF DEMANDS A TRIAL BY JURY

MERCK & COMPANY, INC.

DEFENDANT.

==========X

**PLAINTIFF, JOSE ESCOBAR**, by and through his counsel, **MORELLI RATNER PC**, brings this civil action against **DEFENDANT MERCK & COMPANY, INC.** (hereinafter referred to as "Merck" or "Defendant") and alleges, upon personal knowledge as well as upon information and belief, as follows:

## I. PARTIES

1. This is an action for damages arising from Merck's design, manufacture, inspection, packing, sale, testing, marketing, advertising, promotion, and/or distribution of the unsafe product FOSAMAX® (alendronate sodium), drug of the bisphosphonate class indicated for use in preventing, mitigating or reversing the effects of osteoporosis, glucocorticoid-induced osteoporosis, and Paget's disease.

2. Plaintiff Jose Escobar is an adult citizen of the State of Florida.

3. Defendant is a corporation organized and existing under the laws of the State of New Jersey, with its principal place of business in New Jersey. The Defendant's principal office is located at One Merck Drive, Whitehouse Station, New Jersey.

4. Defendant, either directly or through its agents, apparent agents, servants or employees, at all relevant times, sold or distributed FOSAMAX® in the State of Florida where Plaintiff received a prescription from his doctor and purchased it.

5. At all relevant times, Merck & CO. and/or its predecessors were engaged in the business of researching, designing, testing, manufacturing, inspecting, packaging, marketing, distributing, promoting, advertising, and selling FOSAMAX®.

6. Defendant placed FOSAMAX® into the stream of worldwide commerce and interstate commerce in the United States without adequate testing or a warning of the risk of osteonecrosis of the jaw.

## II. JURISDICTION AND VENUE

7. This Court has jurisdiction pursuant to 28 U.S.C. §§ 1332, as complete diversity exists between Plaintiff and Defendant. Plaintiff is a resident of the State of Florida, and Defendant is incorporated and has its primary place of business in the State of New Jersey. The amount in controversy, exclusive of interest and costs, exceeds $75,000.

8. Venue is proper in this United States Judicial District pursuant to 28 U.S.C. § 1391, because Defendant marketed, promoted, and distributed the dangerous product in this District, thereby receiving substantial financial benefit and profits the dangerous product in New York and nationwide.

## III. FACTUAL BACKGROUND

### A. FACTS REGARDING FOSAMAX® (ALENDRONATE SODIUM)

9. FOSAMAX® (alendronate sodium) was approved in September 1995 and is indicated for preventing, mitigating or reversing the effects of osteoporosis, glucocorticoid-induced osteoporosis, and Paget's disease.

10. At all times relevant, Merck was responsible for, or involved in, designing, manufacturing, marketing, advertising, distributing, and selling FOSAMAX®.

11. FOSAMAX® is within a class of drugs known as bisphosphonates. Bisphosphonates are used for treating bone condition such as osteoporosis and Paget's disease. Other drugs within this class, such as AREDIA® and ZOMETA®, are used as chemotherapy and as adjunct chemotherapy but are not indicated for use in non-cancerous conditions such as osteoporosis.

12. There are two subclasses of bisphosphonates: (a) those that contain nitrogen, e.g. pamidronate (AREDIA®); ibandronate (BONDRONAT®); and alendronate (FOSAMAX®); and (b) those that **do not** contain nitrogen, e.g. etridonate (DIDRONEL®); clodronate (BONEFOS® and LORON®); and tiludronate (SKELID®).

13. Articles and scientific studies in the early-to-mid 1990's reported the frequent occurrence of a condition called osteonecrosis of the jaw in users of bisphosphonates with nitrogen during chemotherapy.

14. Osteonecrosis of the jaw is a serious medical condition that is typically irreversible and can result in severe disability and death.

15. Merck knew or should have known that FOSAMAX®, as a bisphosphonate with nitrogen, has a similar adverse event profiles to the other drugs within this specific subclass of bisphosphonates.

15. Merck knew and or should have known that FOSAMAX® inhibits endothelial cell function like other bisphosphonates with nitrogen.

16. Merck knew or should have known that bisphosphonates with nitrogen inhibit vascularization and induce ischemic changes in the patients' lower jaw (mandibles) and upper jaw (maxillae) and that these ischemic changes are cumulative in nature.

17. Merck knew or should have known that these ischemic changes combine to create a compromised vascular supply in the affected area.

18. Merck knew or should have known that a compromised vascular supply can turn a minor injury or disease into a non-healing wound. A non-healing wound can progress to widespread and typically irreversible osteonecrosis (bone death) and osteomyelitis (inflammation of bone marrow).

19. Osteonecrosis of the jaw and other dental complications among FOSAMAX® users were reported in scientific literature shortly after Merck began selling FOSAMAX®.

20. The FDA's Office of Drug Safety posted its postmarketing safety review on bisphosphonates on August 25, 2004. The review focused on jaw injuries caused by the bisphosphonates pamidronate (AREDIA®), zoledronic acid (ZOMETA®), risedronate (ACTONEL®), and alendronate (FOSAMAX®).

21. The FDA's Office of Drug Safety's postmarketing safety review confirmed earlier scientific and newspaper reports that found that users of FOSAMAX® were experiencing osteonecrosis of the jaw.

22. The FDA's safety review implicated FOSAMAX® specifically in determining that osteonecrosis of the jaw was a class effect.

23. FDA recommended that Merck amend its FOSAMAX® label to specifically warn about the risk of osteonecrosis of the jaw.

24. Defendant refuses the FDA's request and, to this day, still does not adequately warn specifically of the risk of osteonecrosis of the jaw in its FOSAMAX® labeling.

25. Defendant knew, and had reason to know, of these medical problems associated with and related to the use of its product at least as early as August 25, 2004.

26. Defendant continues to mislead physicians and the public by marketing FOSAMAX® without a specific warning about the risk of osteonecrosis despite its knowledge of an increased risk of the condition.

27. Even though Defendant knew or had reason to know of the risk of osteonecrosis of the jaw associated with use of its product, it failed to adequately and sufficiently warn consumers, including Plaintiff Jose Escobar, his prescribing doctor, or the medical community of such risks.

(a) Plaintiff would not have used FOSAMAX® had Defendant properly disclosed the risks associated with this product. Consumers have several safer alternatives to FOSAMAX® for treatment of osteoporosis.

(b) Alternatively, if Plaintiff would have known about the risk of osteonecrosis of the jaw he would have been able to seek treatment and avoid the clinical manifestation of the condition as it currently exists.

28. Defendant, through its affirmative misrepresentations and omissions, actively concealed from Plaintiff and his physicians the true and significant risks associated with taking FOSAMAX®.

**B. FACTS REGARDING JOSE ESCOBAR**

29. Plaintiff Jose Escobar used FOSAMAX® from approximately December 2003 until approximately January 2007.

30. Plaintiff used FOSAMAX® continuously through January 2007 for the prevention and/or treatment of osteopenia to promote healthy bones.

31. As a direct and proximate result of FOSAMAX®, Plaintiff Jose Escobar suffered severe and grievous personal injuries including, but not limited to, falling out of teeth, TMJ Dysfunction, inflammation, swelling and degenerative bone disease, and other bone and jaw injuries, which began developing in or about July 2006.

32. As a direct and proximate result of TMJ dysfunction, and other injuries caused by FOSAMAX®, Plaintiff Jose Escobar needed to have teeth replaced February 2007.

33. This TMJ dysfunction and other jaw injuries, which were caused and will continue to cause Plaintiff's damages, place Jose Escobar at risk of further serious injuries and/or surgeries, and have resulted in a significant and permanent deterioration of ability to use his jaw.

35. Unaware of the risks presented FOSAMAX®, or that FOSAMAX® was the cause of his injuries, Plaintiff continued to use FOSAMAX® until approximately January 2007.

36. At the time of Plaintiff's injuries, Plaintiff was unaware–and could not have reasonably known or learned through reasonable diligence–that such injuries directly resulted from Defendant's negligent and otherwise culpable acts, omissions, and misrepresentation or from Plaintiff's use of FOSAMAX®.

**FIRST CLAIM FOR RELIEF**
**(PRODUCTS LIABILITY - FAILURE TO WARN)**

37. Plaintiff incorporates by reference all preceding paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

38. Defendant had a duty to warn Plaintiff of the risks and/or defects about which it knew or should have known with respect to FOSAMAX®.

39. Defendant failed to adequately warn Plaintiff or Plaintiff's prescribing physician or the medical community of the risks of FOSAMAX® used by the plaintiff.

40. The FOSAMAX® manufactured and/or supplied by Defendant was unreasonably dangerous and defective because FOSAMAX® was not accompanied by proper warnings to Plaintiff regarding all possible adverse side effects associated with the use of FOSAMAX® and the comparative severity, incidence, and duration of such adverse effects.

41. The warnings and information given to Plaintiff did not accurately reflect the symptoms, scope, severity, or frequency of the potential side effects.

42. After Defendant knew or should have known of the risk of injury from FOSAMAX®, Defendant failed to provide adequate warnings to users or consumers of the product, as well as to the medical community; failed to immediately recall or pull the product from retailers' shelves; and in fact continued to aggressively promote the product, and as a direct result thereof, FOSAMAX® manufactured and/or supplied by Defendant, was defective due to inadequate post-marketing warning and/or instructions.

43. Had Plaintiff been adequately warned by Defendant of the dangers of FOSAMAX®, he would not have used FOSAMAX® and would not have been damaged thereby.

44. Had Plaintiff been adequately warned by Defendant of the dangers of FOSAMAX® and its dangers, Plaintiff Jose Escobar could have received medical care to treat for injuries in a more effective manner, and Plaintiff's physicians

would have been alerted to the problem and better prepared to identify and treat infected users of FOSAMAX®, including Plaintiff, more effectively.

45. By reason of the foregoing, Plaintiff was and will be caused bodily injury, pain, suffering and economic loss.

46. Defendant acted with willful disregard for the safety of Plaintiff and regarded profits over the safety of the consumers, such as Plaintiff, to whom the product was sold for use.

47. Defendant acted with callous disregard for the safety of Plaintiff.

48. Plaintiff was caused to suffer the grievous personal injuries and losses described herein as a result of Defendant's willful misconduct.

49. As a direct and proximate consequence of Defendant's acts and omissions, Plaintiff sustained serious personal injuries and related losses.

(a) Plaintiff required and will continue to require healthcare and services.

(b) Plaintiff incurred and will incur medical and related expenses.

(c) Plaintiff suffered and will continue to suffer mental anguish, physical pain and suffering, diminished capacity for the enjoyment of life, a diminished quality of life, diminished ability to work, diminished jaw use, and other losses and damages.

(d) Plaintiff's direct medical losses and costs include hospitalization, physician care, monitoring, treatment, surgeries, medications, and medical supplies.

50. Defendant's conduct was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers, including Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

51. By reason of the foregoing, Plaintiff is entitled to compensatory and punitive damages in a sum to be determined at trial in this matter.

## SECOND CLAIM FOR RELIEF
## (NEGLIGENCE AND RECKLESSNESS)

52. Plaintiff incorporates by reference all of the preceding paragraphs of this Complaint as if fully set forth herein.

53. Defendant owed Plaintiff a duty to exercise reasonable care when designing, manufacturing, inspecting, packaging, marketing, advertising, distributing, and selling FOSAMAX®. This duty included the duty not to introduce a product, such as FOSAMAX®, into the stream of commerce that caused users to suffer from unreasonably dangerous adverse side effects.

54. At all relevant times to this action, Defendant owed a duty to properly warn Plaintiff of the risks, dangers and adverse side effects of its product FOSAMAX®.

55. Defendant failed to exercise proper care in the performance of duties, and Defendant breached its duties, by failing to exercise ordinary care in the preparation, design, research, testing, development, manufacturing, inspection, packaging, labeling, marketing, promotion, advertising, distributing, and selling of FOSAMAX®, including:

(a) failing to use due care in the design, preparation, development, manufacture, inspection, and packaging of FOSAMAX® to prevent the aforementioned risk of injuries to individuals who used the product;

(b) failing to conduct adequate pre-marketing testing and research to determine the safety FOSAMAX®;

(c) failing to conduct adequate post-marketing surveillance to determine the safety of FOSAMAX®;

(d) failing to completely, accurately and in a timely fashion, disclose the results of the pre-marketing testing and post-marketing surveillance and testing to Plaintiff, consumers, the medical community, and the FDA;

(e) failing to accompany FOSAMAX® with proper warnings regarding all possible adverse side effects including, but not limited to, any potential for contracting jaw injuries including ONJ, associated with the use of FOSAMAX®;

(f) being otherwise reckless, careless and/or negligent.

56. Even though Defendant knew and had reason to know that FOSAMAX® caused unreasonable and dangerous side effects, which many users would be unable to remedy by any means, Defendant continued to promote and market FOSAMAX® to consumers, including Plaintiff.

57. Defendant ignored, suppressed and concealed this critical information and continued to market its products by providing false and misleading information and suppressing and concealing the truth with regard to the safety of

FOSAMAX® despite possession of evidence demonstrating that FOSAMAX® caused serious injuries.

58. Defendant knew or should have known that consumers such as Plaintiff would suffer injuries and losses as a result of Defendant's failure to exercise ordinary care as described above, and such injuries were foreseeable.

59. As a direct and proximate consequence of Defendant's acts, omissions, concealment, suppression, and wrongful breaches of duties, and misrepresentation as described herein, Plaintiff sustained serious and grievous personal injuries, which have been painful and debilitating, and caused Plaintiff to suffer related losses.

60. As a direct result of Defendant's wrongful misconduct, Plaintiff has incurred and will continue to incur medical and related expenses.

61. As a direct result of Defendant's wrongful misconduct, Plaintiff also has suffered and will continue to suffer mental anguish, physical pain and suffering, diminished capacity for the enjoyment of life and ability to work to the fullest extent, a diminished quality of life, diminished use of his jaw, and other losses and damages.

62. As a direct result of Defendant's wrongful misconduct, Plaintiff has incurred direct medical losses and costs for hospitalization, physician care, surgery, monitoring, treatment, medications, and medical supplies

63. Defendant owed a duty of reasonable care to Plaintiff to design, manufacture, test, perform quality assurance evaluations, and sell and/or distribute FOSAMAX in a safe condition.

64. Defendant breached its duty by failing to exercise reasonable care and/or was reckless in the manufacture, sale, testing, quality assurance, marketing, packaging, warnings, advertising, promotion, monitoring and warning of adverse events, and/or distribution of FOSAMAX.

65. Defendant's conduct was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers, including Plaintiff, thereby entitling Plaintiff to punitive and exemplary damages so as to punish Defendant and deter it from similar conduct in the future.

66. Defendant's conduct was reckless and beyond all standards of common decency so as to permit the recovery of punitive damages.

67. By reason of the foregoing, Plaintiff was caused bodily injury, pain, suffering and economic losses.

68. As a result of Defendant's wrongful conduct, Plaintiff is entitled to compensatory and punitive damages in a sum to be determined at trial in this matter.

**THIRD CLAIM FOR RELIEF**
**(BREACH OF EXPRESS WARRANTY)**

69. Plaintiff incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein.

70. Defendant expressly represented and warranted to Plaintiff and other consumers that FOSAMAX® was safe and fit for its intended purposes, that it was of merchantable quality, that it did not produce any dangerous side effects, particularly any unwarned of side effects, and that it was adequately tested.

71. These representations and warranties came in the form of:

(a) Defendant's public written and verbal assurances of the safety and efficacy of FOSAMAX®;

(b) Press releases, interviews and dissemination via the media of promotional information, the sole purpose of which was to create an increased demand for FOSAMAX®, which failed to warn of the risk of injuries inherent to the use of FOSAMAX®;

(c) Verbal and written assurances made by Defendant regarding FOSAMAX® and downplaying the risk of injuries associated with the product;

(d) False and misleading written information, supplied by Defendant upon which Plaintiff, the public, and the medical community relied in prescribing or recommending FOSAMAX® during the period of Plaintiff's use of FOSAMAX®; and

(e) Direct-to-Consumer advertisements.

72. The documents referred to above were created by and at the direction of Defendant.

73. Defendant knew or had reason to know that FOSAMAX® did not conform to these express warranties and representations in that FOSAMAX® is neither safe nor as effective as represented, and that FOSAMAX® produces serious and unwanted adverse side effects, as described above.

74. Defendant thereby breached its express representations and warranties.

75. Defendant's express representations and warranties were a part of the basis of the bargain in Plaintiff's purchase and use of Defendant's FOSAMAX® product.

76. FOSAMAX® did not and does not conform to Defendant's express representations because it is not safe, has serious side effects, including unwarned-of side effects, and causes severe and permanent injuries.

77. Plaintiff relied upon Defendant's express warranties.

78. Plaintiff would not have used FOSAMAX® if he understood and appreciated how dangerous the product was.

79. FOSAMAX® was not fit for its intended use; it was defective at the time Plaintiff purchased it.

80. Plaintiff used the product as it was intended to be used.

81. Plaintiff could not have discovered the defect in the exercise of ordinary care.

82. The defect was a substantial factor in causing Plaintiff's injuries.

83. As a direct and proximate consequence of Defendant's act, omission, misrepresentations, and breaches of warranties, Plaintiff required and will continue to require healthcare and services.

(a) Plaintiff has incurred and will continue to incur medical anguish, physical pain and suffering, diminished capacity for the enjoyment of life, a diminished quality of life, diminished ability to work, diminished use of his jaw, and other loss and damages.

(b) Plaintiff's direct medical losses and costs include hospitalization, physician care, monitoring, treatment, surgeries, medications, and medical supplies.

84. Defendant acted with willful disregard for the safety of Plaintiff and regarded profits over the safety of the consumers, such as Plaintiff, to whom the product was sold for use.

85. Defendant acted with callous disregard for the safety of Plaintiff.

86. Plaintiff was caused to suffer the grievous personal injuries and losses described herein as a result of Defendant's willful misconduct.

87. As a direct and proximate consequence of Defendant's acts and omissions, Plaintiff sustained serious personal injuries and related losses.

(a) Plaintiff required and will continue to require healthcare and services.

(b) Plaintiff suffered and will continue to suffer mental anguish, physical pain and suffering, diminished capacity for the enjoyment of life, diminished ability to work, diminished use of his jaw, and other losses and damages.

(c) Plaintiff's direct medical losses and costs include hospitalization, physician care, monitoring, treatment, surgeries, medications, and medical supplies.

88. Defendant's conduct was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers, including Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

89. By reason of the foregoing, Plaintiff is entitled to compensatory and damages in a sum to be determined at trial in this matter.

**FOURTH CLAIM FOR RELIEF**
**(BREACH OF IMPLIED WARRANTY)**

90. Plaintiff incorporates by reference all of the paragraphs of this Complaint as if fully set forth herein.

91. Defendant manufactured, distributed, advertised, promoted, and sold FOSAMAX®.

92. At all relevant times, Defendant knew of the use for which FOSAMAX® was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

93. Defendant was aware that consumers, including Plaintiff, would use FOSAMAX® for the prevention and/or treatment of osteoporosis.

94. Plaintiff reasonably relied upon Defendant's judgment and expertise to sell or recommend FOSAMAX® only if it was indeed of merchantable quality and safe and fit for its intended use.

95. Consumers, including Plaintiff, reasonably relied upon Defendant's implied warranty for FOSAMAX®.

96. FOSAMAX® reached consumers, including Plaintiff, without substantial change in the condition in which it was manufactured and sold by Defendant.

97. Defendant breached its implied warranty to consumers, including Plaintiff.

98. FOSAMAX® was not of merchantable quality or safe and fit for its intended use.

99. FOSAMAX® was not fit for its intended use.

100. FOSAMAX® was defective at the time Plaintiff purchased it.

101. Plaintiff used the product as it was intended to be used.

102. Plaintiff could not have discovered the defect in the product in the exercise of ordinary care.

103. The defect in the product was a substantial contributing factor in causing Plaintiff's injuries, damages and losses.

104. As a direct and proximate consequence of Defendant's acts, omissions, misrepresentations, and breaches of warranties, Plaintiff sustained serious personal injuries and related losses.

(a) Plaintiff required and will continue to require healthcare and services.

(b) Plaintiff incurred and will continue to incur medical and related expenses.

(c) Plaintiff suffered and will continue to suffer mental anguish, physical pain and suffering, diminished capacity for the enjoyment of life, a diminished quality of life, diminished ability to work, diminished use of his jaw, and other losses and damages.

(d) Plaintiff's direct medical losses and costs include hospitalization, physician care, monitoring, treatment, surgeries, medications, and medical supplies.

105. As a direct and proximate consequence of Defendant's acts and omissions, Plaintiff sustained serious personal injuries and related losses.

(a) Plaintiff required and will continue to require healthcare and services.

(b) Plaintiff incurred and will continue to incur medical and related expenses.

(c) Plaintiff suffered and will continue to suffer mental anguish, physical pain and suffering, diminished capacity for the enjoyment of life, a diminished quality of life, diminished ability to work, diminished use of his jaw, and other losses and damages.

(d) Plaintiff's direct medical losses and costs include hospitalization, physician care, monitoring, treatment, surgeries, medications, and medical supplies.

106. Defendant's conduct was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers, including Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

107. By reason of the foregoing, Plaintiff is entitled to compensatory damages in a sum to be determined at trial in this matter.

**FIFTH CLAIM FOR RELIEF**
**(MISREPRESENTATION, CONSTRUCTIVE FRAUD AND FRAUDULENT CONCEALMENT)**

108. Plaintiff incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein.

109. Defendant's superior knowledge and expertise, its relationship of trust and confidence with the public, its specific knowledge regarding the risks and dangers of FOSAMAX®, and its intentional dissemination of promotional and marketing information and advertisements about FOSAMAX® for the purpose of maximizing its sales, each give rise to the affirmative duty to meaningfully disclose and provide all material information about FOSAMAX®'s risks and harms to consumers like Plaintiff.

110. Defendant made fraudulent affirmative and material misrepresentations and omissions, as statements of fact, with respect to FOSAMAX® in the following particulars:

(a) Defendant represented through its labeling, advertising, marketing material, advertisements, and packaging that FOSAMAX® had been tested and was found to be safe and effective for preventing, mitigating or reversing the effects of osteoporosis, glucocorticoid-induced osteoporosis, and Paget's disease;

(b) Defendant omitted in the packaging for this product that FOSAMAX® users have an increased risk of developing osteonecrosis of the jaw, a serious, debilitating, and often irreversible condition in its users, but knew and, at least, had reason to know that product caused the condition;

(c) Defendant represented that FOSAMAX® was safer (or at least as safe) as other alternative bisphosphonates, when, indeed, it was not; and,

111. Defendant made affirmative misrepresentations and fraudulently, intentionally and/or recklessly concealed and suppressed material adverse information regarding the safety and effectiveness of FOSAMAX®.

112. These statements were untrue and were known by Defendant to be untrue at the time Defendant made the statements.

113. Defendant made these misrepresentations and actively concealed adverse information at a time when Defendant knew or had reason to know that FOSAMAX® had defects and was unreasonably dangerous and was not what Defendant had represented to the consuming public, including Plaintiff.

114. Defendant omitted, suppressed and/or concealed material facts concerning the dangers and risk of injuries associated with the use of FOSAMAX® including, but not limited to, osteonecrosis of the jaw.

115. Furthermore, Defendant's purpose was willfully blind to, ignored, downplayed, avoided, and/or otherwise understated the serious nature of the risks associated with the use of FOSAMAX® in order to increase its sales to consumers such as Plaintiff.

116. The representations and concealment were undertaken by Defendant with an intent that Plaintiff would rely upon them, as he did.

117. Defendant's representations and concealments were undertaken with the intent of defrauding and deceiving Plaintiff to induce and encourage the sale of FOSAMAX®.

118. Defendant's fraudulent representations evinced their callous, reckless, willful, and depraved indifference to the health, safety, and welfare of consumers, including Plaintiff.

119. Plaintiff and Plaintiff's doctor justifiably relied on and were induced by Defendant's misrepresentations, omissions, and/or active concealment of the dangers of FOSAMAX® in selecting the FOSAMAX® product.

120. Plaintiff did not know that the representations were false and misleading, and omitted critical and material information about the safety of the product.

121. Plaintiff could not have discovered this information through ordinary means, and was entitled to and was justified in relying upon Defendant's superior skill, knowledge, representations and omissions.

122. Plaintiff would not have purchased or used FOSAMAX® had Plaintiff and Plaintiff's doctor been aware of the increased risk of osteonecrosis of the jaw associated with FOSAMAX® and the relative efficacy of FOSAMAX® compared with other readily available bisphosphonates.

123. As a direct and proximate consequence of Defendant's acts, omissions, concealment and misrepresentations, Plaintiff sustained serious personal injuries and related losses.

(a) Plaintiff required and will continue to require healthcare and services.

(b) Plaintiff incurred and will continue to incur medical and related expenses.

(c) Plaintiff suffered and will continue to suffer mental anguish, physical pain and suffering, diminished capacity for the enjoyment of life, a diminished quality of life, diminished ability to work, diminished use of the jaw, and other losses and damages.

(d) Plaintiff's direct medical losses and costs include hospitalization, physician care, monitoring, surgeries, treatment, medications, and medical supplies.

124. Defendant's conduct was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers, including Plaintiff, thereby entitling Plaintiff to punitive and exemplary damages so as to punish Defendant and deter it from similar conduct in the future.

125. Defendant's conduct was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers, including Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

126. By reason of the foregoing, Plaintiff is entitled to compensatory and punitive damages in a sum to be determined at trial in this matter.

## SIXTH CLAIM FOR RELIEF
## (UNJUST ENRICHMENT)

127. Plaintiff incorporates by reference all previous paragraphs of this Complaint as is fully set forth herein.

128. At all times relevant to this action, Defendant was the manufacturer, seller, and/or supplier of FOSAMAX®.

129. Plaintiff paid for FOSAMAX® in good faith for the purpose of preventing, mitigating or reversing the effects of osteoporosis.

130. Defendant has accepted payment from Plaintiff for the purchase of FOSAMAX®.

131. Plaintiff did not receive the safe and effective product for which one paid for and which one expected to receive from Defendant.

132. Defendant benefited from the transaction, Defendant unjustly failed to provide the product that Plaintiff paid for and expected to receive, and this failure by Defendant was to Plaintiff's detriment and damages.

133. It is thus inequitable and unjust for Defendant to retain this money because Plaintiff did not, in fact, receive the product Defendant represented FOSAMAX® to be.

134. Defendants thus reaped a benefit bestowed by Plaintiff, at Plaintiff's expense.

## SIXTH CLAIM FOR RELIEF
## (PUNITIVE DAMAGES)

135. Plaintiff incorporates by reference all previous paragraphs of this Complaint as is fully set forth herein.

136. Defendant has repeatedly engaged in a pattern of conduct of deliberately avoiding FDA recommendations on known public hazards that should be warned about.

137. For example, Defendant completed a study called VIGOR (VIOXX® Gastrointestinal Outcomes Research) relating to its prescription cox-2 inhibitor VIOXX® in March 2000.

138. The VIGOR study showed that VIOXX® patients had more than double the rate of serious cardiovascular problems than those on Naproxen, an older non-steroidal anti-inflammatory drug.

139. The study was published in the New England Journal of Medicine in November 2000.

140. The FDA warned Defendant in September 2001 to stop misleading doctors about VIOXX®'s effect on the cardiovascular system. The FDA requested that Merck stop minimizing the risks of the drug in its marketing.

141. In complete disregard to the FDA's request Merck refused to adequately warn physicians and patients about the risk of heart attacks and VIOXX®.

142. An FDA representative presented on August 25, 2004 results of a database analysis of 1.4 million patients. The analysis demonstrated that VIOXX® users were more likely to suffer a heart attack or sudden cardiac death than those taking Celebrex or older non-steroidal drugs.

143. The FDA representative concluded that VIOXX® was linked to more than 27,000 heart attacks or sudden cardiac deaths nationwide from the time it came on the market in 1999 through 2003.

144. Defendant released a press statement on August 26, 2004 which refuted the FDA's analysis and restated Defendant's support for the cardiovascular safety of VIOXX.

145. Defendant recalled VIOXX® from the market on September 30, 2004, after having to halt the APPROVe study (Adenomatous Polyp Prevention on Vioxx). The study was underway to evaluate the use of VIOXX® for recurrent colon polyps. The researchers found an alarming number of cardiovascular events among the drug's users in the APPROVe study.

146. Defendant was aware that as of August 24, 2004 the FDA was advising Defendant to warn about the risk of osteonecrosis of the jaw in its FOSAMAX® label.

147. Because Defendant knew that its blockbuster drug VIOXX® was about to be pulled from the market, Defendant deliberately chose to not amend its FOSAMAX® label to include the risk of osteonecrosis of the jaw fearing that such a warning would result in a reduced revenues for FOSAMAX®, its second largest income producer.

148. Defendant's inaction places more importance on the $3 billion+ annual sales of FOSAMAX® than the health of consumers, including the Plaintiff.

149. Defendant's acts were willful and malicious in that Defendant's conduct was carried on with a conscious disregard for the safety and rights of Plaintiff.

150. Defendant's unconscionable conduct thereby warrants an assessment of exemplary and punitive damages against Defendant in an amount appropriate to punish Defendant, and deter similar conduct in the future.

## PRAYER FOR RELIEF

WHEREFORE, Plaintiff requests the following relief:

- Compensatory damages;
- Disgorgement of profits;
- Restitution;
- Punitive and exemplary damages;
- Pre-Judgment and post-judgment interest as provided by law;
- Recovery of Plaintiff's costs including but not limited to, discretionary Court costs, and those costs available under the law, as well as expert fees and attorneys' fees and expenses, and costs of this action;
- Recovery of all amounts by which Defendant was unjustly enriched at expense or detriment of Plaintiff;
- Treble damages available under the General Business Law; and,
- Such other and further relief as the Court deems just and proper.

## VIII. DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury on all counts and issues so triable.

Dated this 28 day of April, 2008.

MORELLI RATNER PC

David S. Ratner, Esq.
Victoria J. Maniatis, Esq.
950 Third Avenue
New York, NY 10022
(877) 751-9800
Attorney for Plaintiff